K091245

SECTION 5 – 510(k) Summary or 510(k) Statement

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92

APPLICANT: Bio Protech

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NOV 30 2009

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CONTACT PERSON: Ms. Anna Kim

OFFICIAL CORRESPONDENT: Ms. Judy Burton, Advena Ltd.

ADDRESS: 2626 Valley View Lane, Suite 4, Dallas, Texas 75234-6274

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DATE OF SUMMARY: November 25, 2009

TRADE NAME: MAXEMS 1000 / MAXEMS 2000

COMMON NAME: EMS

CLASSIFICATION NAME: Stimulator, Muscle, Powered

CLASSIFICATION CODE: IPF

REGULATION NO.: 890.5850

PREDICATE DEVICES: K072795 EMS 5.O / K020750 EV-807 Digital EMS

DEVICE DESCRIPTION:

The MAXEMS are battery operated pulse generators that send electrical impulses through electrodes to the body and reach the underlying muscle group. The devices are provided with two controllable output channels, each independent of each other. An electrode pair can be connected to each output channel. Use of legally marketed, standard carbon film electrodes with a biocompatible adhesive, that are a minimum of 48mmx48mm in size and have an impedance of less than 2k ohms is recommended. The MAXEMS 1000 is an analogue unit with dual channels and a selectable pulse rate of 5, 30, and 100 Hz. The MAXEMS 2000 is a digital unit with an adjustable pulse rate from 1 to 150Hz.

INTENDED USE:

1. Relax muscles
2. Prevention or retardation of disuse atrophy
3. Increasing local blood circulation
4. Muscle re-education
5. Immediate post-surgical stimulation of calf muscle to prevent venous thrombosis
6. Maintaining or increasing range of motion

DETERMINATION OF SUBSTANTIAL EQUIVALENCE BASED ON CLINICAL DATA:
No clinical data has been included in this submission.

CONCLUSIONS DRAWN FROM NON-CLINICAL TESTS:
The MAXEMS series is as safe and effective as the predicate devices cited above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Bio Protech, Inc.
% Advena, Ltd.
Ms. Judy Burton
Director of US Operations
2626 Valley View Lane, Suite 4
Dallas, Texas 75234-6274

NOV 30 2009

Re: K091248
Trade Name: MAXEMS, Models 1000 and 2000
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulation Class: Class II
Product Code: IPF
Dated: November 10, 2009
Received: November 18, 2009

Dear Ms. Burton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

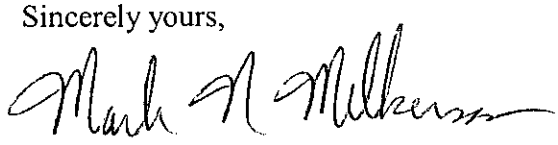
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 – Indications for Use Statement

Indications for Use

510(k) Number (if known):

Device Name: MAXEMS 1000 / MAXEMS 2000

Indications For Use:

1. Relax muscles
2. Prevention or retardation of disuse atrophy
3. Increasing local blood circulation
4. Muscle re-education
5. Immediate post-surgical stimulation of calf muscle to prevent venous thrombosis
6. Maintaining or increasing range of motion

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IFNEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FOR M. MELKERSON

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091248